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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/544,683	04/07/2000	Antonius Arnoldus Christiaan Jacobs	99471 US	1432
31846	7590	02/23/2004	EXAMINER	
INTERVET INC 405 STATE STREET PO BOX 318 MILLSBORO, DE 19966			PORTNER, VIRGINIA ALLEN	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 02/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/544,683

Applicant(s)

JACOBS ET AL.

Examiner

Ginny Portner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 20 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-3,9 and 18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 1-3 and 9 is/are allowed.
- 6) ☐ Claim(s) 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-3, 9 and 19 are pending and have been amended to recite the phrase “essentially free of anti-flagellar antibodies”.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Allowable Subject Matter

1. Claims 1-3 and 9 define over the prior art of record in light of the data provided for chicken antibody compositions without anti-flagella antibodies contained therein to provide a protective immune response upon challenge and therefore are allowed.

Rejections Withdrawn

2. Claims 1-3, 9 and 18 rejected under 35 U.S.C. 112, first paragraph (New Matter), as failing to comply with the written description requirement has been obviated in light of the amendment of the claims to recite the phrase “essentially free of anti-flagellar antibodies”.

3. Claims 1-3, 9 and 18 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, has been obviated through amendment of the claims to recite the phrase “essentially free of anti-flagellar antibodies”.

4. Claims 1-3 rejected under 35 U.S.C. 102(b) as being anticipated by Cawthraw et al has been obviated through amendment of the claims to recite the phrase “essentially free of anti-flagellar antibodies”.

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5. Claims 1-3, 9 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Tsubokura has been obviated through amendment of the claims to recite the phrase “essentially free of anti-flagellar antibodies”.

New Claim Limitations/New Grounds of Rejection

Claim Rejections - 35 USC § 102

6. Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by Dolby et al (Reference of record, 1986) as evidenced by Blaser et al (1983).

Dolby et al disclose the instantly claimed invention directed to:

A vaccine (see Table 3, page 147, protection conferred to challenged young) for the protection of *Campylobacter* (title) colonization in animals (mice)

(see Dolby page 146, Tables 2-4, Vaccine antibody titers (see Table 3) “0” titer for anti-flagella antibodies for strain SF-2, cage numbers 65 and 97);

consisting essentially of an effective amount of antiserum raised to a flagellaless

Campylobacter strain

(see Table 2, non-flagellated vaccines in dams and their ability to protect young against oral infection with strain 8116)

wherein the antiserum recognizes a 97 kD(+/- 5 kD), a 60 kD(+/- 5 kD) and a 13 kD (+/- 3 kD) band on a Western blot

(While Dolby et al did not analyze the antiserum produced by the flagella-less whole cell strain of *Campylobacter jejuni* on a Western blot, the antiserum raised against the strain was a protective composition of antiserum that protected against challenge in 38% of the challenge animals. Evidence is provided by Blaser et al that *Campylobacter* strains comprise the recited antigens (see Blaser et al, page 282, col. 1, (14,000 aka 14 kD); Figure 10 page 282, (61,000 and 89,000 aka 61 kD and 89 kD).

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6. the vaccine essentially free of anti-flagellar antibodies.

(see Dolby, Table 3, page 147, Maternal anti-flagella titers for Fla- strains in cages 65 and 97 were "0" which defines a composition of protective antiserum which is essentially free of anti-flagella antibodies).

Inherently Dolby et al anticipates the instantly claimed invention. *Atlas Powder Co. v. IRECA*, 51 USPQ2d 1943, (FED Cir. 1999) states "Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art...However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. "The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art".

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

8. Blaser et al (July 1986) is cited to show a flagellaless strain of *Campylobacter jejuni* and the whole cell antigen profile (see page 48, Figure 1) to show the presence of about 97, 60 and 13 kDa antigens are present in the whole cell flagellaless strain.

9. Diker et al (1992) is cited to show flagellaless variants of *Campylobacter jejuni*, see page 134, Materials and Methods; and page 136, paragraph 1).

10. Huyer et al (1986) is cited to show *Campylobacter jejuni* porin protein naturally occurs in an oligomeric complex of about 92,000 (see page 249, col. 1, bottom of first paragraph).

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¶ 11. McSweegan, E et al (1987) is cited to show an antiserum that has had the flagellum antibodies adsorbed out (see page 1433, col. 1, Table 3, Rabbit no 71 sIgA titer 80 after removal of anti-flagella antibodies).

¶ 12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

¶ 13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on 8:30-6:00 M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
February 12, 2004

L. F. S.
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